- (ii) In the event of an unplanned change in activity or condition, the Department shall immediately cease emplacement of waste in the disposal system if the Department determines that one or more of the following conditions is true:
- (A) The containment requirements established pursuant to §191.13 of this chapter have been or are expected to be exceeded:
- (B) Releases from already-emplaced waste lead to committed effective doses that are or are expected to be in excess of those established pursuant to §191.15 of this chapter. For purposes of this paragraph (b)(3)(ii)(B), emissions from operations covered pursuant to part 191, subpart A of this chapter are not included; or
- (C) Releases have caused or are expected to cause concentrations of radionuclides or estimated doses due to radionuclides in underground sources of drinking water in the accessible environment to exceed the limits established pursuant to part 191, subpart C of this chapter.
- (iii) If the Department determines that a condition described in paragraph (b)(3)(ii) of this section has occurred or is expected to occur, the Department shall notify the Administrator, in writing, within 24 hours of the determination. Such notification shall, to the extent practicable, include the following information:
- (A) Identification of the location and environmental media of the release or the expected release;
- (B) Identification of the type and quantity of waste (in activity in curies of each radionuclide) released or expected to be released;
- (C) Time and date of the release or the estimated time of the expected release:
- (D) Assessment of the hazard posed by the release or the expected release; and
- (E) Additional information requested by the Administrator or the Administrator's authorized representative.
- (iv) The Department may resume emplacement of waste in the disposal system upon written notification that the suspension has been lifted by the Administrator.

- (v) If the Department discovers a condition or activity that differs significantly from what is indicated in the most recent compliance application, but does not involve conditions or activities listed in paragraph (b)(3)(ii) of this section, then the difference shall be reported, in writing, to the Administrator within 10 calendar days of its discovery.
- (vi) Following receipt of notification, the Administrator will notify the Secretary in writing whether any condition or activity reported pursuant to paragraph (b)(3) this section:
- (A) Does not comply with the terms of the certification; and, if it does not comply,
- (B) Whether the compliance certification must be modified, suspended or revoked. The Administrator or the Administrator's authorized representative may request additional information before determining whether modification, suspension or revocation of the compliance certification is required.
- (4) Not later than six months after the Administrator issues a certification, and at least annually thereafter, the Department shall report to the Administrator, in writing, any changes in conditions or activities pertaining to the disposal system that were not required to be reported by paragraph (b)(3) of this section and that differ from information contained in the most recent compliance application.

§ 194.5 Publications incorporated by reference.

- (a) The following publications are incorporated into this part by reference:
- (1) U.S. Nuclear Regulatory Commission, NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories," published February 1988; incorporation by reference (IBR) approved for §§ 194.22, 194.23 and 194.27.
- (2) American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard, NQA-1-1989 edition, "Quality Assurance Program Requirements for Nuclear Facilities;" IBR approved for §194.22.

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(3) ASME NQA-2a-1990 addenda, part 2.7, to ASME NQA-2-1989 edition "Quality Assurance Requirements for Nuclear Facility Applications;" IBR approved for §194.22 and §194.23.

(4) ASME NQA-3-1989 edition, "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" (excluding section 2.1 (b) and (c)); IBR approved for §194.22.

- (b) The publications listed in paragraph (a) of this section were approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected or obtained from the Air Docket, Docket No. A-92-56, room M1500 (LE131), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, or copies may be inspected at the Office of the Federal Register, 800 N. Capitol Street NW, 7th floor, Suite 700, Washington, DC, or copies may be obtained from the following addresses:
- (1) For ASME standards, contact American Society of Mechanical Engineers, 22 Law Drive, P.O. Box 2900, Fairfield, NJ 07007–2900, phone 1–800–843–2763
- (2) For Nuclear Regulatory Commission documents, contact Division of Information Support Services, Distribution Service, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or contact National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, phone 703–487–4650.

§ 194.6 Alternative provisions.

The Administrator may, by rule pursuant to 5 U.S.C. 553, substitute for any of the provisions of this part alternative provisions chosen after:

- (a) The alternative provisions have been proposed for public comment in the FEDERAL REGISTER together with information describing how the alternative provisions comport with the disposal regulations, the reasons why the existing provisions of this part appear inappropriate, and the costs, risks and benefits of compliance in accordance with the alternative provisions;
- (b) A public comment period of at least 120 days has been completed and

public hearings have been held in New Mexico:

- (c) The public comments received have been fully considered; and
- (d) A notice of final rulemaking is published in the FEDERAL REGISTER.

§ 194.7 Effective date.

The criteria in this part shall be effective on April 9, 1996. The incorporation by reference of certain publications listed in the criteria is approved by the Director of the Federal Register as of April 9, 1996.

§ 194.8 Approval process for waste shipment from waste generator sites for disposal at the WIPP.

- (a) Quality Assurance Programs at Waste Generator Sites. The Agency will determine compliance with requirements for site-specific quality assurance programs as set forth below:
- (1) Upon submission by the Department of a site-specific quality assurance program plan the Agency will evaluate the plan to determine whether it establishes the applicable Nuclear Quality Assurance (NQA) requirements of §194.22(a)(1) for the items and activities of §8194.22(a)(2)(i), 194.24(c)(3) and 194.24(c)(5). The program plan and other documentation submitted by the Department will be placed in the dockets described in §194.67.
- (2) The Agency will conduct a quality assurance audit or an inspection of a Department quality assurance audit at the relevant site for the purpose of verifying proper execution of the sitespecific quality assurance program plan. The Agency will publish a notice in the FEDERAL REGISTER announcing a scheduled inspection or audit. In that or another notice, the Agency will also solicit public comment on the quality assurance program plan and appropriate Department documentation described in paragraph (a)(1) of this section. A public comment period of at least 30 days will be allowed.
- (3) The Agency's written decision regarding compliance with the requisite quality assurance requirements at a waste generator site will be conveyed in a letter from the Administrator's authorized representative to the Department. No such compliance determination shall be granted until after